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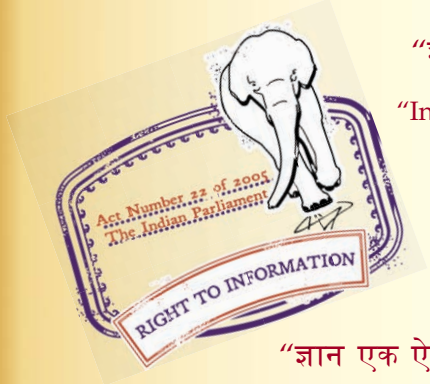
IS 4445 (1967): Filter and Filter Chamber for Blood Transfusion [MHD 12: Hospital Equipment]



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IS : 4445 - 1967
(Reaffirmed 1977)
(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR FILTER AND FILTER CHAMBER FOR BLOOD TRANSFUSION

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NEW DELHI 110002

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February 1968

Indian Standard

SPECIFICATION FOR FILTER AND FILTER CHAMBER FOR BLOOD TRANSFUSION

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SPECIFICATION FOR FILTER AND FILTER CHAMBER FOR BLOOD TRANSFUSION

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 11 December 1967, after the draft finalized by the Medical Glass Instruments and Appliances Sectional Committee had been approved by the Consumer Products Division Council.

0.2 Preparation of standards on surgical instruments, medical equipment and apparatus including medical glass instruments has been taken up at the instance of the Advisory Committee for Development of Surgical Instruments, Equipment and Appliances (Government of India).

0.3 Great need has been felt for the standardization of glass instruments used in pathological work and blood transfusion. This standard covering the essential requirements of blood transfusion filter and filter chamber is expected to help in providing uniform equipment to all laboratories.

0.4 Assistance has been derived from B.S. 2463 : 1962 'Transfusion equipment for medical use' issued by the British Standards Institution.

0.5 This standard is one of a series of Indian Standards on medical glass apparatus. Other specifications published so far in the series are:

IS : 3740-1966 Tubes, glass for pathological work

IS : 3741-1966 Tubes, sedimentation

IS : 3742-1966 Pipettes, dilution for haemocytometers

IS : 4067-1967 Tube, swab (West type), for throat

IS : 4068-1967 Ureometer, Doremus type

IS : 4069-1967 Urinometer

IS : 4087-1967 Pipette for haemoglobinometers and blood pipette for biochemical work

IS : 4363-1967 Drip counter

IS : 4364-1967 Pipettes, serological

IS: 4444-1967 Bottles bacteriological

0.6 This standard contains clause **7.1** which calls for agreement between the purchaser and the supplier.

0.7 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This specification covers the requirements of filter and filter chamber used in the blood transfusion apparatus.

2. MATERIALS

2.1 The filter tube and chamber shall be made from clear, colourless, neutral glass (for definition *see* IS : 1382-1961†). The glass shall pass the alkalinity test prescribed in IS : 2303-1963‡ for Type I glass.

2.2 The filter shall be made from silk.

2.3 The bung shall be made from rubber, conforming to IS : 3692-1965§.

3. SHAPE AND DIMENSIONS

3.1 The shape and dimensions shall be as given in Fig. 1.

4. WORKMANSHIP AND FINISH

4.1 The filter tube and chamber shall be well-annealed, free from bubbles and as far as possible, free from striae, stones and other visible defects (for definitions *see* IS : 1382-1961†). The ends shall be smoothly rounded in the flame. It shall be capable of being easily cleaned. It shall pass the thermal shock test, dry heat test and autoclave test specified in **5.1**, **5.2** and **5.3** respectively.

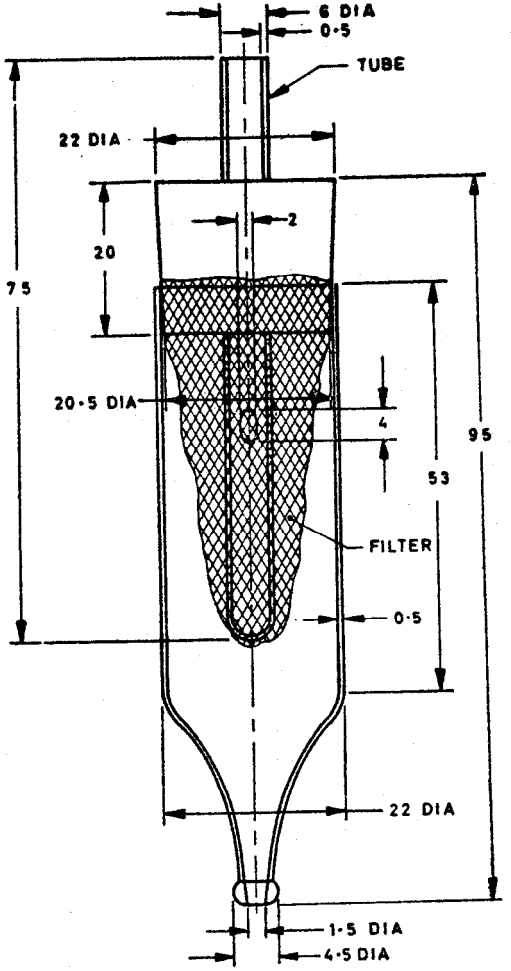
4.2 The filter shall have a filtering area of not less than 32 cm^2. The filter material shall be minimum of 80 percent as efficient as a sieve having a mesh with an average pore size of 0·212 mm square and a thread of 0·1 mm diameter (the reference filter material). The filter shall be disposed of after using it for one transfusion.

*Rules for rounding off numerical values (*revised*).

†Glossary of terms relating to glass industry.

‡Method of grading glass for alkalinity.

§Specification for rubber closures (pharmaceutical).



All dimensions in millimetres (Nom).

FIG. 1 FILTER AND FILTER CHAMBER FOR BLOOD TRANSFUSION

5. TESTS

5.1 Thermal Shock Test — The filter tube and chamber shall be boiled in water for 30 minutes, then transferred to water at about 20°C. The glass shall not develop any chipping or cracking.

5.2 Dry Heat Test — The filter tube and chamber shall be subjected to a dry heat test in a sterilizing oven at 180° ± 2°C for 30 minutes. The glass shall not show deterioration in any way nor develop any crack or chipping.

5.3 Autoclave Test — The filter tube and chamber shall be autoclaved at a steam pressure of 1·4 kg/cm² for a period of 30 minutes. The glass shall not show deterioration in any way nor develop any crack or chipping.

6. MARKING

6.1 The filter and chamber shall be marked with the name of the manufacturer, his initials or trade-mark.

6.1.1 The filter and chamber may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

7. PACKING

7.1 The filter tube and chamber shall be packed as agreed to between the manufacturer and the purchaser. However, the recommended procedure is as follows:

'Each set of filter tube and chamber shall be wrapped in suitable paper and packed in lots of 24 in suitable cartons'.

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